DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M2947M

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

September 13, 1999

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Harold V. Lorton, Chief Executive Officer
Lorton's Fresh Squeezed Juices
735 East Base Line Street
San Bernardino, CA 92410

W/L 44-9

Dear Mr. Lorton:

We inspected your orange juice manufacturing facility located at 735 East Base Line Street, San Bernardino, CA 92410 between June 28 and August 3, 1999 and found that you manufacture and distribute unpasteurized (i.e., not heat treated) juice products under the following labels:

"NATURAL BRAND'S FRESH SQUEEZED GRAPEFRUIT JUICE, 64 FL. OZ."
"NATURAL BRAND'S FRESH SQUEEZED GRAPEFRUIT JUICE, 12 FL. OZ."
"FRESH SQUEEZED Grapefruit Juice"
"Tangerine Juice 100% NATURAL FRESH SQUEEZED JUICE"
"NATURAL BRAND'S FRESH SQUEEZED ORANGE JUICE, 16 FL. OZ."
"NATURAL BRAND'S FRESH SQUEEZED ORANGE JUICE, 32 FL. OZ."
"Lorton's Fresh Squeezed Juice 100% Pure ORANGE JUICE"
"WIMAN'S 100% FRESHLY SQUEEZED ORANGE JUICE 128 FL. OZ."
"KING JUICE, CO. 100% FRESH PULP SQUEEZED ORANGE JUICE"
"VOILA! FRESHLY SQUEEZED LEMON JUICE"
"VOILA! FRESHLY SQUEEZED ORANGE JUICE"
"VOILA! FRESHLY SQUEEZED LIME JUICE"
"VOILA! FRESHLY SQUEEZED GRAPEFRUIT JUICE"

All unpasteurized juice products being manufactured and distributed at your facility under the above labels are misbranded within the meaning of Sections 403(a)(1) and 201(n) of the Federal Food, Drug and Cosmetic Act. They are misbranded because the products do not bear the warning statement required by 21 CFR 101.17(g)(2) and they are not exempt from this labeling requirement because you are not processing the juice in a manner that has been validated to achieve a 5-log reduction of pertinent microorganisms.

Our inspection revealed that the control measures and practices you have implemented do not match those used in the 5-log reduction validation study conducted for you [redacted]. Therefore, your unpasteurized juices are not processed in a manner demonstrated to achieve a 5-log reduction of pertinent microorganisms. Your validation study at the pilot plant employed

the following: [redacted] However, our inspection showed that you are not implementing these parameters since you are [redacted] This large range cannot be interpreted as consistently achieving a 5-log reduction.

Since you receive bulk unpasteurized juice via tanker trucks for blending with other juice, you must ensure that this bulk juice has been processed in a manner to provide 5-log reduction or any juice product made from this juice would also have to bear the warning statement.

The above violation concerns certain labeling requirements and is not intended to be an all-inclusive list of deficiencies of your labels or your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. You must take prompt action to either correct your labels by including the warning statement or apply a process that is demonstrated to consistently achieve a 5-log reduction of pertinent microorganisms. We may initiate regulatory action without further notice if you do not correct these deficiencies. Regulatory action can include seizure and/or injunction. You should also ensure that all insanitary conditions that we observed during our inspection are corrected. We provided you a list of these problems on the FDA-483.

We request that you notify this office in writing, within 15 working days of receipt of this letter, of the specific actions taken to correct the noted violations and prevent their recurrence. If you cannot complete corrective action within 15 working days, you should state the reason for the delay and the time within which corrections will be completed. Your written response should contain the following information: i) a list of all unpasteurized juice products currently in production at your facility including an estimate of how much of each product is currently in distribution, ii) where each product was distributed and iii) under what label each product was distributed. Please direct your response to the attention of:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Sincerely,

Thomas L. Sawyer

Acting District Director